Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: December 5, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–33343 Filed 12–31–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0493]

Gerard T. O'Brien; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Gerard T. O'Brien has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a mixture of hydrogen peroxide and sodium bicarbonate as an antimicrobial agent on fresh poultry.

DATES: Written comments on the petitioner's environmental assessment by February 3, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3078.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7A4530) has been filed by Gerard T. O'Brien, 2162 Skyline Dr., Gainesville, GA 30501. The petition proposes to amend the food additive regulations to provide for the safe use of a mixture of hydrogen peroxide and sodium bicarbonate as an antimicrobial agent on fresh poultry.

FAP 7A4530 was submitted to the agency on September 24, 1987, as FAP 7A4045. On March 9, 1992, because of continued deficiencies in the petition, which the agency had not filed, FDA notified the petitioner that it would not continue its review of this petition. Information concerning microbiological and chemical studies, which the agency had requested in several letters to the petitioner, had not been submitted. These studies were needed to demonstrate the bactericidal effectiveness of the petitioned use of the additive and the dietary exposure to oxidation products that might be formed on the chicken during processing. Therefore, FDA planned no further review.

Since that time, the agency has been corresponding with the petitioner and has still not received the requested information. In a September 18, 1995, letter to FDA the petitioner asked whether he had exhausted his administrative remedies. Before receiving a response from FDA, the petitioner filed a lawsuit against the agency. After the dismissal of this lawsuit, the agency responded to the petitioner's original question in an October 16, 1996, letter saying that the petitioner had not exhausted his administrative remedies and that he could either file a new petition that would include the supplemental information requested by the agency or send a written request to FDA asking the agency to file the petition as submitted in accordance with § 171.1(i)(1) (21 CFR 171.1(i)(1)). The petitioner responded in a November 4, 1996, letter indicating that he wants FDA to approve the proposed use of this additive and does not intend to supplement the petition. Therefore, FDA is filing the petition as submitted, in accordance with § 171.1(i)(1). The agency has assigned a new number (FAP 7A4530) to this petition for administrative purposes.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the original petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before February 3, 1997 submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: December 12, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–33380 Filed 12–31–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0353]

Determination of Regulatory Review Period for Purposes of Patent Extension; DIFFERIN Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DIFFERIN Solution and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.